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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/169,048	10/08/98	HUSE W	P-IX-3280

HM22/0228

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EXAMINER	
GARCIA, M	
ART UNIT	**PAPER NUMBER**
1627	10

DATE MAILED: 02/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/169,048	Huse et al
Examiner	**Group Art Unit**
Maurie E. Garcia, Ph. D.	1627

☒ Responsive to communication(s) filed on *Dec 27, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *ONE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-38* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-38* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Please note: The number of Art Unit 1618 has been changed to 1627. Please direct all correspondence for this case to **Art Unit 1627**.

Sequence Compliance

1. The Communication pertaining to sequence compliance filed January 12, 2000 is acknowledged. However, there were errors detected in the processing of the computer readable form (CRF) as set forth in the attached printout and Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. Therefore, this application still fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply and correction is required.

Election/Restriction

2. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1618 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for

allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a method for determining binding of a receptor to one or more ligands, classified in any of class 435, subclasses 4-29 depending on the receptor and ligand, for example, class 435, subclasses 7.6 or 7.8.

II. Claims 10-18, drawn to a method for determining binding of a ligand to one or more receptors, classified in any of class 435, subclasses 4-29 depending on the receptor and ligand, for example, class 435, subclasses 7.6 or 7.8.

III. Claims 19-25, drawn to a second method for determining binding of a ligand to one or more receptors, classified in any of class 435, subclasses 4-29 depending on the receptor and ligand, for example, class 435, subclasses 7.6 or 7.8.

IV. Claims 26-31, drawn to a method for identifying an optimal binding ligand variant, classified in any of class 435, subclasses 4-29 depending on the receptor and ligand, for example, class 435, subclasses 6, 7.1 or 7.2.

V. Claims 32-38, drawn to a second method for identifying an optimal binding ligand variant, classified in any of class 435, subclasses 4-29 depending on the receptor and ligand, for example, class 435, subclasses 6, 7.1 or 7.2.

4. The inventions are distinct, each from the other, because of the following reasons:

5. Groups I - V are different methods. The methods are different because they use different steps, require different reagents and will produce different products and/or results.

They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. The differences between the methods are set forth below.

6. In the instant case, the methods of Groups I, II & III are different from those of Groups IV & V because Groups I, II & III are simply methods to determine binding while Groups III & IV are methods to identify ligands. These methods therefore have different steps and different end results, i.e. the methods of Groups III & IV require additional steps of identifying the ligands and result in the identification of an optimal binding ligand.

7. Group I is different from Groups II & III because Group I is a method for determining binding of a receptor to one or more ligands, while Groups II & III deal with methods for determining binding of a ligand to one or more receptors. Group I involves the use of a collective receptor variant population and Group II involves the use of a collective ligand variant population, which represent different starting materials. Additionally, Group III involves the use of a collective ligand population, without any requirement that this be a variant population, and is furthermore drawn to determining binding to a (single) receptor or variant thereof. In contrast, Group II is drawn to determining binding to one or more receptors and Group I is drawn to determining binding to one or more ligands.

8. The methods of Groups IV & V are different from each other because they involve different steps and different reagents. Group IV requires contacting the receptor population with a ligand population while Group V requires contacting the receptor population with an

individual ligand. Additionally, Group IV further requires dividing the ligand population into subpopulations after detecting binding. Group V has the requirement of dividing the receptor population into subpopulations first, then detecting binding of the individual ligands and finally further dividing these into two or more new subpopulations.

9. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter and would require different searches. Please note that even though some of these groups could be classified in the same class/subclass, this has no effect on the non-patent literature search. The different inventions listed would require completely different searches in these databases, and there is no expectation that the searches would be coextensive. Therefore an undue search burden exists and restriction for examination purposes as indicated is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 8:30 to 6:00 and alternate Fridays.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KEITH D. MacMILLAN
PRIMARY EXAMINER

Maurie E. Garcia, Ph.D.
February 22, 2000

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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EXAMINER	
Maurie E. Garcia, Ph. D.	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED:

Notice to Comply

Please find below a communication from the EXAMINER in charge of this application

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Any inquiry concerning this communication should be directed to Examiner **Maurie E. Garcia, Ph. D.**, Art Unit **1627**, whose telephone number is **(703) 308-0065.**

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

APPLICANT IS GIVEN A ONE MONTH EXTENDABLE PERIOD WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Application No.: 09/169,048

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

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